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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,879	06/16/2005	Florence Henry	C 2766 PCT/US	6323
23657	7590	03/06/2007	EXAMINER	
COGNIS CORPORATION PATENT DEPARTMENT 300 BROOKSIDE AVENUE AMBLER, PA 19002			CLARK, AMY LYNN	
			ART UNIT	PAPER NUMBER
			1655	
SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE		DELIVERY MODE	
3 MONTHS	03/06/2007		PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/539,879	HENRY ET AL.	
	Examiner Amy L. Clark	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 28 November 2006.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 12-33 is/are pending in the application.
- 4a) Of the above claim(s) 12,13,16-23,26,29,32 and 33 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 14,15,24,25,27,28,30 and 31 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    - Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>06/16/2005</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
|   | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION*****Election/Restrictions***

Applicant's election with traverse of Group III, claims 14, 15, 24, 25, 27, 28, 30, and 31 in the reply filed on 12 October 2006 and Applicant's election of "Arginin A" as Specie A in the reply filed on 28 November 2006 is acknowledged. The traversal is on the ground(s) that only one invention has been made and that the application of an extract of Argania spinosa to treat four different conditions by application of the extract to the skin. Applicant further argues that the claims have unity of invention in that they all relate to an extract of Argania spinosa and application of the extract to the skin. Applicants submit that they have found that application of the Argania spinosa extract to the skin provides remarkable treatment for the conditions set forth. Applicant further argues that arganin A and proteins are generally present in the extracts of Argania spinosa unless the extracts have been especially treated to remove the components from the extract. This is not found persuasive because MPEP 1850 (II) states:

"An international application should relate to only one invention or, if there is more than one invention, the inclusion of those inventions in one international application is only permitted if all inventions are so linked as to form a single general inventive concept (PCT Rule 13.1). With respect to a group of inventions claimed in an international application, unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" is defined in PCT Rule 13.2 as meaning those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art. The determination is made on the contents of the claims as interpreted in light of the description and drawings (if any).

Whether or not any particular technical feature makes a "contribution" over the prior art, and therefore constitutes a "special technical feature," should be considered with respect to novelty and inventive step. For example, a document discovered in the international search shows that there is a presumption of lack of novelty or inventive

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step in a main claim, so that there may be no technical relationship left over the prior art among the claimed inventions involving one or more of the same or corresponding special technical features, leaving two or more dependent claims without a single general inventive concept.

See also MPEP 1893.03(d):

"When making a lack of unity of invention requirement, the examiner must (1) list the different groups of claims and (2) explain why each group lacks unity with each other group (i.e., why there is no single general inventive concept) specifically describing the unique special technical feature in each group".

The principles of unity of invention are used to determine the types of claimed subject matter and the combinations of claims to different categories of invention that are permitted to be included in a single international or national stage patent application. See MPEP § 1850 for a detailed discussion of Unity of Invention. The basic principle is that an application should relate to only one invention or, if there is more than one invention, that applicant would have a right to include in a single application only those inventions which are so linked as to form a single general inventive concept.

A group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature. The expression special technical features is defined as meaning those technical features that define the contribution which each claimed invention, considered as a whole, makes over the prior art. For example, a corresponding technical feature is exemplified by a key defined by certain claimed structural characteristics which correspond to the claimed features of a lock to be used with the claimed key."

Claim 32, at least, is anticipated by or obvious over Hatinguais et al. (Reference N, FR 2553788A1, Translation of abstract only) Hatinguais teaches a stable lipid extract of argan fruit in apolar solvent for use in the field of skin cosmetology. Consequently, the special technical feature which links the claims does not provide a contribution over the prior art, so unity of the invention is lacking.

The requirement is still deemed proper and is therefore made **FINAL**.

Claims 12-33 are currently pending.

Claims 12,13, 16-23, 26, 29, 32 and 33 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 12 October 2006.

**Claims 14, 15, 24, 25, 27, 28, 30, and 31 are under examination.**

***Information Disclosure Statement***

The information disclosure statement (IDS) was submitted on 16 June 2005. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Please note that any references that have been lined through have not been considered because no English translations was provided by Applicant. In the case where "Abstract only" is written next to a reference, the Examiner only considered the abstract because that was the only part of the document translated into English.

***Specification***

The disclosure is objected to because of the following informalities: please correct the terms: "arganin A", "arganin B", "arganin C", "arganin D", "arganin E", "arganin F", "arganin G", "arganin H", "arganin J" and "misaponin A" with their appropriate spellings on pages 4 and 5 of the specification. The correct spellings are arginine A, arginine B, arginine C, arginine D, arginine E, arginine F, arginine G, arginine H, arginine J, and mi-saponin A. Please also stay consistent with writing

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abbreviations. For example, on page 1 of the specification, Applicant abbreviates 5-dihydrotestosterone as "5-DHT", however, throughout the remainder of the specification, Applicant uses the abbreviation "DHT". The switch to "DHT" is confusing because it is unclear if Applicant is referring to "5-DHT" or if Applicant intends "DHT" to be an abbreviation for something else.

Appropriate correction is required.

The use of the trademark SkinEthic® has been noted in this application. It should be accompanied by the generic terminology (See page 10).

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: An *in vitro* method of determining the quantity of transformed testosterone.

### ***Claim Objections***

Claims 14 and 15 are objected to because of the following informalities: "Argania spinosa" should be written in italics to read like Argania spinosa. Appropriate correction is required.

Claims 27 and 28 are objected to because of the following informalities: the terms "arganin A", "arganin B", "arganin C", "arganin D", "arganin E", "arganin F", "arganin G", "arganin H", "arganin J" and "misaponin A" are misspelled. The correct spellings are arginine A, arginine B, arginine C, arginine D, arginine E, arginine F, arginine G, arginine H, arginine J, and mi-saponin A. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14, 15, 24, 25, 27, 28, 30, and 31 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of making a saponin crude extract of an *Argania spinosa* cake (from the seeds after extraction of the oil), which was defatted with hexane (1 hour at 80°C), wherein the defatted cake was then dried for 24 hours at room temperature and the defatted and dried cake were made up with 80% by vol. ethanol in a stirred vessel, stirred for 16 hours at room temperature, the solids were then removed by filtration and the filtered solution forms the crude extract from which ethanol was removed by evaporation, and the residue was freeze-dried (See page 9), an *in vitro* method of determining transepidermal diffusion, and an *in vitro* method of determining the quantity of transformed testosterone, does not reasonably provide enablement for a method for reducing the activity of anti-5- $\alpha$ -reductase which comprises: applying to the affected area of the skin to be treated a

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composition containing an anti-5- $\alpha$ -reductase effective amount of a preparation containing an anti-5- $\alpha$ -reductase effective amount of any extract of the plant *Argania spinosa* (claim 14) or any method for reducing the activity of anti-5- $\alpha$ -reductase which comprises: applying to the affected area of the skin to be treated a composition containing an anti-5- $\alpha$ -reductase effective amount of a preparation containing an anti-5- $\alpha$ -reductase effective amount of an extract of the plant *Argania spinosa* for treatment of unwanted hair growth in women which comprises: applying to the area of the skin where hair growth is not wanted a hair growth retarding effective amount of preparation containing an extract of the plant *Argania spinosa* (claim 15). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make any invention commensurate in scope with these claims.

Claims 14, 15, 24, 25, 27, 28, 30, and 31 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. A method for reducing the activity of anti-5- $\alpha$ -reductase which comprises: applying to the affected area of the skin to be treated a composition containing an anti-5- $\alpha$ -reductase effective amount of a preparation containing an anti-5- $\alpha$ -reductase effective amount of an extract of the plant *Argania spinosa* (claim 14) and a method for reducing the activity of anti-5- $\alpha$ -reductase which comprises: applying to the affected area of the skin to be treated a composition containing an anti-5- $\alpha$ -reductase effective amount of a preparation containing an anti-5- $\alpha$ -reductase effective amount of an extract of the plant *Argania spinosa* for treatment of unwanted hair growth in women which comprises: applying to the area of the skin where hair growth is not wanted a hair growth retarding effective amount of preparation

containing an extract of the plant *Argania spinosa* (claim 15) critical or essential to the practice of the invention, but not included in the claims is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). In view of the breadth of the claims and the lack of guidance provided by the specification as well as the unpredictability of the art, the skilled artisan would have required an undue amount of experimentation to make and/or use the claimed invention. Therefore, Claims 14, 15, 24, 25, 27, 28, 30, and 31 are not considered to be fully enabled by the instant specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14, 15, 24, 25, 27, 28, 30, and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The metes and bounds of claims 14 and 15 are rendered uncertain by the phrase "A method for reducing the activity of anti-5- $\alpha$ -reductase which comprises: applying to the affected area of the skin to be treated a composition containing an anti-5- $\alpha$ -reductase effective amount of a preparation containing an anti-5- $\alpha$ -reductase effective amount of an extract of the plant *Argania spinosa*" (claim 14) and the phrase "A method for reducing the activity of anti-5- $\alpha$ -reductase which comprises: applying to the affected area of the skin to be treated a composition containing an anti-5- $\alpha$ -reductase effective amount of a preparation containing an anti-5- $\alpha$ -reductase effective amount of an extract

of the plant *Argania spinosa* for treatment of unwanted hair growth in women which comprises: applying to the area of the skin where hair growth is not wanted a hair growth retarding effective amount of preparation containing an extract of the plant *Argania spinosa*" (claim 15). because it is unclear as to what Applicant means by "reducing the activity of anti-5- $\alpha$ -reductase" and "containing an anti-5- $\alpha$ -reductase effective amount of a preparation containing an anti-5- $\alpha$ -reductase effective amount of an extract of the plant *Argania spinosa*". Is Applicant trying to say that the composition reduces the activity of 5- $\alpha$ -reductase or is Applicant saying that the composition reduces the activity of anti-5- $\alpha$ -reductase? If Applicant is saying that the composition reduces the activity of anti-5- $\alpha$ -reductase, see the above rejection under 112 1<sup>st</sup> paragraph. The lack of clarity renders the claims indefinite since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy L. Clark whose telephone number is (571) 272-1310. The examiner can normally be reached on 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Amy L. Clark  
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February 8, 2007

*Susan Coe Hoffman*  
2-20-07  
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